

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft guidance to the Division of Inspectorate Policy, Office of Inspections and Investigations, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Patrick Clouser, Office of Inspections and Investigations, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852, 240-402-5276, [Patrick.Clouser@fda.hhs.gov](mailto:Patrick.Clouser@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

FDA is announcing the availability of a draft guidance document entitled "Questions and Answers Regarding Mandatory Cosmetics Recalls: Guidance for Industry." The purpose of this draft guidance document, when finalized, is to provide guidance to industry on the implementation of the mandatory cosmetics recall provisions of section 611 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), which was added by section 3502 of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). The guidance is in the form of Questions and Answers and provides answers to common questions that might arise about these mandatory recall provisions and FDA's current thinking regarding their implementation.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA

on mandatory cosmetics recalls. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

#### **II. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### **III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>.

**Lowell M. Zeta,**

*Acting Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-23249 Filed 12-17-25; 8:45 am]

**BILLING CODE 4164-01-P**

### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **National Institutes of Health**

#### **Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Child Health and Human Development Council.

*Date:* March 20, 2026.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate to review and evaluate grant applications.

*Address:* Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes, 6710B Rockledge Drive, Bethesda, MD 20817.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Rebekah S. Rasooly, Ph.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20817, Phone: 301-827-2599, Email: [Rebekah.rasooly@nih.gov](mailto:Rebekah.rasooly@nih.gov).

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/advisory/council>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: December 15, 2025.

**David W. Freeman,**

*Supervisory Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-23216 Filed 12-17-25; 8:45 am]

**BILLING CODE 4140-01-P**

### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **National Institutes of Health**

#### **Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA: NIH Blueprint and BRAIN Initiative Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience (D-SPAN) Award (F99/K00 Clinical Trial Not Allowed).

*Date:* January 21, 2026.

*Time:* 9:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

**Contact Person:** Gek Ming Sia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-3341, [gekming.sia@nih.gov](mailto:gekming.sia@nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; Fellowships: Disease Management, Risk, Prevention and Health Behavior.

**Date:** January 21, 2026.

**Time:** 9:30 a.m. to 12:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Address:** National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

**Meeting Format:** Virtual Meeting.

**Contact Person:** Christiane M. Robbins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, (301) 451-4989, [crobbs@mail.nih.gov](mailto:crobbs@mail.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; RFA Panel: Topics in Clinical Care and Health Interventions.

**Date:** January 21, 2026.

**Time:** 10:00 a.m. to 1:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Address:** National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

**Meeting Format:** Virtual Meeting.

**Contact Person:** Karen Nieves Lugo, Ph.D., MPH Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 7201 Wisconsin Ave, Ste 533, Bethesda, MD 20892, 301-402-1366, [karen.nieveslugo@nih.gov](mailto:karen.nieveslugo@nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; Special Topics in Biochemistry and Biophysics.

**Date:** February 3-4, 2026.

**Time:** 10:00 a.m. to 6:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Address:** National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

**Meeting Format:** Virtual Meeting.

**Contact Person:** John J. Laffan, Ph.D., Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18J, Bethesda, MD 20892, (301) 443-7154, [laffanjo@mail.nih.gov](mailto:laffanjo@mail.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel; PAR-21-321: Cancer Center Support Grant.

**Date:** February 13, 2026.

**Time:** 10:00 a.m. to 6:00 p.m.

**Agenda:** To review and evaluate grant applications.

**Address:** National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

**Meeting Format:** Virtual Meeting.

**Contact Person:** Eun Ah Cho, Ph.D., Scientific Review Officer, Cancer Diagnosis, Prevention & Therapeutics (CDPT), Center for Scientific Review, National Cancer Institute, NIH 6701, Rockledge Drive, Bethesda, MD 20892, (301) 496-3591, [choe@mail.nih.gov](mailto:choe@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 15, 2025.

**Sterlyn H. Gibson,**

*Program Specialist, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-23214 Filed 12-17-25; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Child Health and Human Development Council, January 26, 2026, 12:00 p.m. to January 27, 2026, 05:00 p.m., Eunice Kennedy Shriver National Institute of Child, Health and Human Development National Institutes, 6710 B Rockledge Drive, Bethesda, MD 20817 which was published in the **Federal Register** on September 24, 2025, 90 FR 45955.

The originally scheduled two-day meeting was changed to a one-day meeting that will be held on January 26, 2026, from 12:00 p.m. to 05:00 p.m. The January 26, 2026, meeting is open to the public and its agenda will cover the open meeting agenda topics from the initial **Federal Register** Notice. The topics that were originally intended to be covered in the closed session will be discussed in a new meeting scheduled for March 20, 2026. A new **Federal Register** notice will be provided to the public with the March 20, 2026, meeting details.

Dated: December 15, 2025.

**David W. Freeman,**

*Supervisory Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-23215 Filed 12-17-25; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### NIH Controlled-Access Data Policy and Proposed Revisions to NIH Genomic Data Sharing Policy

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health (NIH) is requesting public input on its proposal to establish harmonized and transparent policy requirements for protecting human participant research data. Specifically, NIH proposes (1) establishing policy requirements for which data should be controlled-access under NIH data sharing policies, and (2) revising the NIH Genomic Data Sharing Policy to simplify and harmonize requirements.

**DATES:** To ensure consideration, comments must be submitted in writing by March 18, 2026.

**ADDRESSES:** Comments may be submitted electronically to <https://osp.od.nih.gov/comment-form-draft-nih-controlled-access-data-policy-and-proposed-revisions-to-nih-genomic-data-sharing-policy/>.

Comments are voluntary and may be submitted anonymously. You may also voluntarily include your name and contact information with your response. Other than your name and contact information, please do not include in the response any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. After the NIH Office of Science Policy (OSP) has finished reviewing the responses, the responses may be posted to the OSP website without redaction.

**FOR FURTHER INFORMATION CONTACT:** Taunton Paine, Director, Division of Scientific Data Sharing, NIH Office of Science Policy, at (301) 496-9838 or [SciencePolicy@od.nih.gov](mailto:SciencePolicy@od.nih.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

NIH serves as the steward of a wide range of research data and continuously works to optimize open sharing with appropriate protections throughout the entire data lifecycle. Given its numerous established data policies, NIH is proposing a holistic update to its data policy framework to strengthen data protections, clarify requirements, and reduce duplicative burden.

First, NIH is proposing a new NIH Controlled-Access Data Policy to support the research community in fulfilling NIH data sharing expectations. This proposed policy specifies human participant data types required to be managed via controlled-access and provides criteria for assessing the need for controls for other data types. It also provides a standard set of expectations across NIH Institutes, Centers and